HIV/AIDS Section Workgroup on ADAP Meeting Summary June 15, 2016

Roll Call

Members Present: Paul Arons, Steven Badura, Jeff Beal, Carol Broxton, Martha Buffington, Valentino Clarke, Kristine Collins, Michael D'Amico, Annie Farlin, Leonard Jones, Diedre Kelly, Marcia King, Jimmy Llaque, Joe May, Paul McKeel, Elizabeth Sherman, James Talley, Debbie Taylor, Bonnie Tiemannn

Guest: Tammy Cuyler, Kim Molnar and Michelle Scavnicky,

Moment of Silence for Pulse Shooting Victims

Introduction of New Members

ADAP Consumers (Alternates) Lorenza Haines – Big Bend Cares Christine Collis – FDOH Alachua County, PLWH

PLWH

Karen Creary - Children's Diagnostic and Treatment Center

Ryan White Part C Representative Marcia King, ARNP – Unconditional Love

Members to Vote on March 16, 2016 Meeting Minutes (Dr. Beal and Annie Farlin)

Motion to Approve – Elizabeth Sherman 2nd – Martha Buffington Minutes unanimously approved

Patient Care Update (Joe May) HRSA Site Visit Update

- HRSA conducted Comprehensive Site Visit, February 9-11, 2016.
- Received report on May 17, 2016.
- HAS must write a letter acknowledging receipt of the report and whether or not we agree recommendations and suggestion made. The letter is due to HRSA July 8, 2016.
- A Corrective Action Plan template will come from HRSA prescribing the format they would like the activities tracked.
- Shelley Taylor-Donahue was recently hired as the Community Programs Unit Supervisor. She will be joining the staff July 5, 2016 and her arrival will be helpful in addressing the issues identified through the HRSA site visit.

Review of General Findings

- Fiscal
 - Improve fiscal tracking mechanisms and capability related to tracking caps on administration, planning, evaluation, quality monitoring, etc.
 Need to tie more directly to client-level activities.
 - Improve fiscal monitoring of sub recipients. Want to ensure that when site visits are being conducted that fiscal activities are also being monitored.
 - Look at rebate funds. What activities and projects would be appropriate? Encouraged to use resources to their fullest advantage.
- Administrative (Program Management)
 - Address staff vacancies
 - Hire consultants to look at overall service delivery model. Conduct and analysis of the efficiency of the program and evaluate whether or not there is a better way to deliver services to our clients. For example, instead of having a Part B Consortia structure, to look at other options such as a direct service provision.
 - Have more written internal operating procedures in the Community Programs area and a more structured staff orientation and training.
- Clinical Quality Management
 - Increase spending on clinical quality management (up to \$3 million) programs and processes. Use those funds to build the capacity needed. Currently working to set up an Executive Committee to provide oversight to the program.

ADAP

- Did not have a standard time frame for an expectation of services to be approved. Want ADAP to come up with a more standardized expectation of when clients can expect to receive services
- Improve monitoring of local HD that program eligibility is being determined uniformly and accurately
 - Release as soon as possible update manual
- Simplify eligibility process.
- Maximize the number of persons that we are providing services for.
 Perhaps raising the eligibility criteria to 4x Federal Poverty Level (FPL) for persons to be considered for movement into the marketplace.

Q: Paul Arons- Besides ADAP specific recommendations, do the rebate recommendations mentioned in the Fiscal area also apply to ADAP? A: Yes, it applies to all.

- Rebate dollars are generated through ADAP. Currently have \$30 million in rebate dollars. Seems our hands are tied in using these funds.
- Rebate funds must be spent in the year in which they are collected. Must liquate those before grant funds.

Q: Quality management – Is there a template being created?

A: It is being developed with our lead agencies. Must be submitted by end of current year, and implemented by the end of the program year. Need to ensure that there is some standardization among all.

Establishing Standards of Care (SOC) for the Ryan White Part B Program

- Inviting everyone on the ADAP workgroup to participate in this process.
- The time commitment would be 1 hour every two weeks to start.
- Dr. Beal will review other state's SOC and take from it best practices to present to the group.
- Targeted completion date of August 2016.

ADAP Formulary Update – New Drugs

- Email sent out on May 27, 2016 announcing that both Descovy and Odefsey added to the formulary through state pharmacy system or CVS Caremark.
- Gilead has decided that due to low utilization to voluntarily withdraw single-agent Viteka globally in February 2017. ADAP has no clients that are currently on this regimen.

Planning for the next Marketplace Open Enrollment

- Starts on November 1, 2016.
- Currently review processes and procedures to address any deficiencies and strengthen our processes. Looking at ways to streamline enrollment process, eliminate unnecessary steps, and expand services for clients.
- Program requirements are proving not to be as restrictive as originally interpreted. Striving to increase access to care to meet the needs of clients including other primary care needs as well.
 - Expand benefits for the 2017 such as assisting clients whose income is above 2.5x FPL.
 - Assisting clients with plans in other tiers such as gold, platinum, and (perhaps) diamond. And assisting clients with other marketplace plans from other carriers. Currently able to assist with Florida Blue, United Healthcare, and Molina health plans.
 - Determine a plan of action to assist those clients whose income falls below 1.0x FPL.
- Meeting in Orlando August 4, 2016 with area HAPCs and Ryan White partners around the state to discuss and plan collaboratively
 - Will give update at next meeting.

Q – Marcia King – It took 6 months for their agency to be credentialed through Blue Cross when the initial ADAP got started. When additional carriers are selected, can that information be shared with the group so that they can begin the credentialing process? A: When additional carriers are selected, the information will be shared statewide so that planning can begin at the local level as well.

Q: Leonard Jones— Provide Part As with as much detail as possible so that they can provide you with feedback to let you know what impact it would have at the local level. A: Yes

Q: Martha Buffington— Any information on United Healthcare and their decision not to use CVS anymore?

A: Little information thus far. We are hopeful that with the new PBM fewer clients will be affected and there will be more pharmacy choices and not exclusive to CVS.

New ADAP Database, Provide Enterprise (PE) Update.

- Last stages of testing the new software.
- The President of Groupware Technologies (GTI) came from Wisconsin to give the ADAP Central staff a first real look at the shell of the Provide Enterprise (PE).
- Working with the Section's Data Integration Team, the PBM, and third-party
 payer to configure, test, and update the data connections. Also working to ensure
 that it meets or exceeds the Department's security requirements.
- The new system will allow us to capture all data necessary to make decisions in the ADAP program. The flexibility of the program is a key component of the new software. That flexibility requires the program to have policies and procedures in place. Any future changes and updates to any federal or state rules will be able to be incorporated.
- Paul McKeel is the assigned Contract Manager and he will be working with the HAPCs to get participation of a select group of county staff to test the new software in the very near future.
- Steven Badura, ADAP Operations and Compliance Manager, will help facilitate trainings throughout the state.
 - Tentative in late August 2016
- The deployment with bring a web-interface for clients to access a web portal to apply online for services.
- On schedule for fall of 2016 for the statewide rollout.

PBM Procurement Update

- Final contract has been reviewed and approved.
- Anticipated that the signed contract will be ready by July 1st.
- Without a signed contract we are limited in what information can be shared with the group.
- Once the contract has been fully-executed, information will be shared with stakeholders.

ADAP Policy Manual

- Released June 15, 2016 effective July 1, 2016.
- The document is a working document and will be updated based on the implementation of the new software program.
 - Revamping the training strategy. Increase face-to-face training around the state and inviting everyone who serves an ADAP client to participate. Expand face-to-face trainings throughout the state.

- Basics of ADAP a quick introduction and orientation for anyone who serves an ADAP client in the continuum of care
- Another training specifically for ADAP workers to better serve clients

Mr. Llaque thanked the group for their comments and feedback.

Q: Dr. Beal – Will the workgroup be able to suggest the expansion of the ADAP formulary to include other drugs?

A: Yes. In fact, a member of the ADAP team has compiled a list of drugs that are covered through other the Ryan White Part A programs and Part B formularies to see what the gaps might be or categories that might not be currently funded through ADAP formulary.

Q: Paul Arons – Dr. Beal, would this fit in with the Part B workgroup we discussed? A: I think the ADAP workgroup would be a first to work on that.

Q: If there is an ongoing set of meetings happening, should there be separate meetings to discuss adding new categories of medications to the formulary?

A: Start between medical section and ADAP and then move on from there.

Q: Paul Arons – Do you have any numbers of people who are having interruptions in their coverage?

A: Jimmy Llaque – Will compile a report for the current year. Last year about 8-10% (about 300) of clients faced some sort of challenge with policy cancellations. This year we were tracking but the messaging was a little clearer.

Pilot Program for HCV Treatment Enrollment Update

- Total of 12 clients have been approved.
- Tracking medication pick-up.
 - 5 have received their medications
 - Tammy Kyler is closely monitoring the program and contacting when timely pick-ups have not occurred.
- Discouraging that the number of clients enrolled is so low.

Collaboration with the University of Florida

- The University of Florida has ongoing branch that treats individuals that have hepatitis C that includes the medications needed. The program is run by Dr. David Nelson
- There will be several sites statewide. The project is just getting underway.
- There is ongoing discussion to see if the ADAP pilot patients could be included in their program as well. This would allow the total number of patients ADAP to enroll because the medication would be provided by some entity other than ADAP.

- They have agreed that whenever they find or see an ADAP patient, they will go
 through the normal process of this clinical trial. And if the patient is selected to
 receive Harvoni they would run through the Section's pilot program.
- We would get the data from the program so that we could include it in the Section's reporting

The ADAP Price Task Force has been working with the manufacturers to negotiate better pricing. Progress has been made with AbbVie (Viekira Pak) and Merck (Zepatier) have come to an agreement with the Task Force which is run by National Alliance of State and Territorial AIDS Directors (NASTAD). Pending are answers from Bristol Meyers Squibb (BMS) and Gilead. An announcement is supposed to come out next week regarding those final results.

June 28, 2016 the FDA will rule on the new Gilead product which is a combination of sofosbuvir/velpatasvir (pan-genotypic NS5B/NS5A inhibitors).

Q: Bonnie Tiemann – Want to confirm that we are still limited to two sites for the pilot. A: It is now statewide. Any ADAP eligible within the state of Florida will be able to access the pilot program.

Debbie Taylor – Will email forms directly to the workgroup.

Q. Jeff Beal - Do all members get the ADAP policy manual? If it hasn't we will make sure that it does.

A: We will make sure that happens, if it hasn't already.

Ways to Disseminate Information

How do we get the information out that ADAP has this pilot program?

Kristine Collins – Has disseminated the information to those clients she works with who she knows qualify.

Jimmy Llaque – Acknowledge that there is a flyer under development. Working with pharmacies to include this flyer in with patient's prescription bag.

Valentino Clarke – Now that it has been streamlined he believes that there should be an uptick in the number of people who register.

Paul Arons – You raise another point about streamlining. Originally, during enrollment there was a requirement for a fibrosis score which involved either a blood-draw or some kind of access to a fibro-scan machine. We've determined that the online version of calculated scores based on existing lab information will actually suffice for our purposes. This should remove an added burden.

Q: James Talley – Wouldn't ADAP manager/case worker have this information readily available?

A: With the new data management system, we certainly expect that information will be requested. Many patients don't really know if they are infected. In the future hopefully this is an enhancement that we requested be added to the new PE.

Leonard Jones is going to send letter to medical network to talk about and advertise this project.

Q: Bonnie Tiemann – What is the targeted number of patients we are trying to serve? A: We can serve between 100-125 enrollees. As a reminder this is for Genotype 1 non-cirrhotic patients. Stable cirrhotic patients can get an exception with a referral from their provider.

Updated Tool for Fibrosis Testing

- Forms were revised to include the website that can be used to calculate fibrosis.
 - This online portal can utilize existing lab information will suffice and should remove a barrier to enrollment.
 - It is also the preferred method since it is the most cost-effective.

Closing Comments:

Please let Dr. Beal or Annie know if you do not want to be a participant in the Standards of Care Ryan White Part B meetings.

With no other business, the meeting was adjourned at 4:11 PM. The next meeting is scheduled for September 24, 2016 at 3PM.